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| APPLICATION NO.                     | FILING DATE     | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.    | CONFIRMATION NO. |
|-------------------------------------|-----------------|----------------------|------------------------|------------------|
| 09/715,876                          | 11/18/2000      | John E. Edwards JR.  | 259/064                | 7636             |
| 34313 759                           | 7590 02/18/2004 |                      | EXAMINER               |                  |
| ORRICK, HERRINGTON & SUTCLIFFE, LLP |                 |                      | DEVI, SARVAMANGALA J N |                  |
| 4 PARK PLAZA                        | 4               |                      |                        |                  |
| SUITE 1600                          |                 |                      | ART UNIT               | PAPER NUMBER     |
| IRVINE, CA 92614-2558               |                 |                      | 1645                   |                  |
|                                     |                 |                      | DATE MAILED: 02/18/200 | 4                |

Please find below and/or attached an Office communication concerning this application or proceeding.

| 2   | Application No.  | Applicant(s)   |  |  |  |  |
|---|--|--|--|--|--|--|
|   | 09/715,876   | EDWARDS ET AL.   |  |  |  |  |
| Office Action Summary   | Examiner   | Art Unit   |  |  |  |  |
|   | S. Devi, Ph.D.   | 1645   |  |  |  |  |
| The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply  |  |  |  |  |  |  |
| A SHORTENED STATUTORY PERIOD FOR REPLY THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a reply If NO period for reply is specified above, the maximum statutory period was preply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b). | ole(a). In no event, however, may a reply be time within the statutory minimum of thirty (30) days will apply and will expire SIX (6) MONTHS from cause the application to become ABANDONE | nely filed s will be considered timely. the mailing date of this communication. O (35 U.S.C. § 133). |  |  |  |  |
| Status  |  |  |  |  |  |  |
| 1)⊠ Responsive to communication(s) filed on <u>16 October 2003</u> .  |  |  |  |  |  |  |
| 2a) ☐ This action is <b>FINAL</b> . 2b) ☒ This  | This action is <b>FINAL</b> . 2b)⊠ This action is non-final.   |  |  |  |  |  |
| 3) Since this application is in condition for allowan   | Since this application is in condition for allowance except for formal matters, prosecution as to the merits is  |  |  |  |  |  |
| closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.   |  |  |  |  |  |  |
| Disposition of Claims   |  |  |  |  |  |  |
| 4) Claim(s) 1.3 and 9 is are pending in the application.  |  |  |  |  |  |  |
| 4a) Of the above claim(s) is/are withdrawn from consideration.  |  |  |  |  |  |  |
| 5) Claim(s) is/are allowed.   |  |  |  |  |  |  |
| 6)⊠ Claim(s) <u>1,3 and 9</u> jø/are rejected.  |  |  |  |  |  |  |
| 7) Claim(s) is/are objected to.   |  |  |  |  |  |  |
| 8) Claim(s) are subject to restriction and/or   | election requirement.  |  |  |  |  |  |
| Application Papers  |  |  |  |  |  |  |
| 9) The specification is objected to by the Examiner   | ſ <b>.</b>   |  |  |  |  |  |
| 10)☐ The drawing(s) filed on is/are: a)☐ accepted or b)☐ objected to by the Examiner.   |  |  |  |  |  |  |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).   |  |  |  |  |  |  |
| Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  |  |  |  |  |  |  |
| 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.  |  |  |  |  |  |  |
| Priority under 35 U.S.C. § 119  |  |  |  |  |  |  |
| <ul> <li>12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</li> <li>a) ☐ All b) ☐ Some * c) ☐ None of:</li> <li>1. ☐ Certified copies of the priority documents have been received.</li> </ul>  |  |  |  |  |  |  |
| 2. Certified copies of the priority documents have been received in Application No  |  |  |  |  |  |  |
| 3. Copies of the certified copies of the priority documents have been received in this National Stage   |  |  |  |  |  |  |
| application from the International Bureau   | (PCT Rule 17.2(a)).  |  |  |  |  |  |
| * See the attached detailed Office action for a list of   | of the certified copies not receive  | d.   |  |  |  |  |
|   |  |  |  |  |  |  |
| Attachment(s)   | <u></u>  |  |  |  |  |  |
| 1) Notice of References Cited (PTO-892)   | (PTO-413)  |  |  |  |  |  |
| <ul> <li>2) Notice of Draftsperson's Patent Drawing Review (PTO-948)</li> <li>3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)</li> </ul>   | Paper No(s)/Mail Da 5) Notice of Informal Pa   | te<br>atent Application (PTO-152)  |  |  |  |  |
| Paper No(s)/Mail Date   | 6) Other: Sequence rep   |  |  |  |  |  |

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## **DETAILED ACTION**

# **Request for Continued Examination**

1) A request for continued examination under 37 C.F.R 1.114, including the fee set forth in 37 C.F.R 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 C.F.R 1.114, and the fee set forth in 37 C.F.R 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 C.F.R 1.114. Applicants' submission filed on 09/22/03 has been entered.

# Applicants' Amendment

2) Acknowledgment is made of Applicants' amendment filed 10/16/03 in response to the final Office Action mailed 06/18/03. With this, Applicants have amended the specification.

#### **Status of Claims**

3) Claims 1 and 3 have been amended via the amendment filed 10/16/03.

New claim 9 has been added via the amendment filed 10/16/03.

Claims 1, 3 and 9 are pending and are under examination.

#### **Prior Citation of Title 35 Sections**

4) The text of those sections of Title 35 U.S. Code not included in this action can be found in a prior Office Action.

#### **Prior Citation of References**

The references cited or used as prior art in support of one or more rejections in the instant Office Action and not included on an attached form PTO-892 or form PTO-1449 have been previously cited and made of record.

# Objection(s) Withdrawn

6) The objection to the specification made in paragraph 5 of the Office Action mailed 06/18/03 is withdrawn in light of Applicants' amendment to the specification.

#### Objection(s) Maintained

7) The objection to the drawing made in paragraph 5 of the Office Action mailed 04/09/03 (paper no. 11) is maintained for reasons set forth therein. Applicants have assured the Office that they would submit the required formal drawings upon the receipt of the Notice of Allowability.

## Specification

8) The amendment made at line 6 of page 10 of the specification: (SEQ ID NO: 7) ... 'corresponding to the' polypeptide sequence ..... SEQ ID NO: 8 is confusing and is therefore objected to. Since the polypucleotide sequence corresponds to SEQ ID NO: 7 and the polypeptide sequence corresponds to SEQ ID

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NO: 8, it is suggested that Applicants replace the recitation with --(SEQ ID NO: 7) which encodes the polypeptide sequence of Als1p (SEQ ID NO: 8)--.

## Rejection(s) Withdrawn

- 9) The rejection of claims 1 and 3 made in paragraph 8 of the Office Action mailed 04/09/03 (paper no. 11) and maintained in paragraph 18 of the Office Action mailed 06/18/03 under 35 U.S.C § 112, first paragraph, as containing inadequate written description, is withdrawn.
- The rejection of claims 1 and 3 made in paragraph 8 of the Office Action mailed 04/09/03 (paper no. 11) and maintained in paragraph 18 of the Office Action mailed 06/18/03 under 35 U.S.C § 112, first paragraph, as containing inadequate written description, is withdrawn. A modified rejection to cover the claims, as amended, is set forth below.
- The rejection of claim 1 made in paragraph 21(a) of the Office Action mailed 06/18/03 under 35 U.S.C § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claim.
- 12) The rejection of claim 1 made in paragraph 21(b) of the Office Action mailed 06/18/03 under 35 U.S.C § 112, second paragraph, as being indefinite is withdrawn in light of Applicants' amendment to the claim.
- 13) The rejection of claim 3 made in paragraph 21(c) of the Office Action mailed 06/18/03 under 35 U.S.C § 112, second paragraph, as being indefinite is withdrawn in light of Applicants' amendment to the claim.
- 14) The rejection of claim 9 made in paragraph 21(d) of the Office Action mailed 06/18/03 under 35 U.S.C § 112, second paragraph, as being indefinite is withdrawn in light of Applicants' amendment to the claim.
- The rejection of claims 1 and 3 made in paragraph 12 of the Office Action mailed 04/09/03 (paper no. 11) and maintained in paragraph 19 of the Office Action mailed 06/18/03 under 35 U.S.C. § 102(b) as being anticipated by Hoyer *et al.* (*J. Bacteriol.* 180: 5334-5343, October 1998) (Hoyer *et al.*, 1998), is withdrawn. A modified rejection to cover the claims, as amended, is set forth below.
- The rejection of claims 1 and 3 made in paragraph 14 of the Office Action mailed 04/09/03 (paper no. 11) and maintained in paragraph 20 of the Office Action mailed 06/18/03 under 35 U.S.C. § 103(a) as being unpatentable over Hoyer *et al.* (*Mol. Microbiol.* 15: 39-54, 1995 Applicants' IDS) (Hoyer *et al.*, 1995), is withdrawn. A modified rejection that covers the claims, as amended, is set forth below.

#### Response to Applicants' Arguments on Hoyer et al.

17) With regard to Hoyer et al. (1998), Applicants submit that the amended claim includes the structural

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limitation of a carrier for injection or infusion and defines that the 'vaccine' composition produces an effective immune response. Applicants contend that there is no meaningful disclosure in Hoyer's (1998) reference of a formulation of the N-terminal als1 protein together with a carrier to yield an effective result as a 'vaccine'.

With regard to Hoyer et al. (1995), Applicants state that Hoyer et al. do not disclose any useful immunological function for the alsl protein and do not reach the necessary conclusion from merely speculating that the alsl protein has a potential role in the adhesion function. Applicants contend that the amended claims recite a composition that does not inherently possess the same function as the protein molecule disclosed by Hoyer et al., because Hoyer et al. do not disclose a vaccine formulation that includes a carrier or an N-terminal fragment, or which has been demonstrated to yield any immune response.

Applicants' arguments have been carefully considered, but are non-persuasive. First, the instant claims are not directed to a 'vaccine'. Secondly, even if they did, as set forth previously, the term 'vaccine' represents the intended use and has no patentable weight. Instant claims 1 and 3, as amended currently, do not define the claimed N-terminal fragment structurally. The claimed N-terminal protein fragment does not exclude Hoyer's protein (1998 or 1995). Since the claimed N-terminal fragment of claims 1 and 3 is not identified by one or more structural limitations, it includes or encompasses Hoyer's or any other isolated and purified N-terminal fragment protein of Candida albicans. Hoyer et al. (1998) do teach the claimed composition comprising a biocompatible carrier (see the art rejection made below). The functional limitation, on which the prior art reference is allegedly silent, is considered as an inherent property inseparable from the prior art protein fragment. Where the only difference between the claimed product and the prior art product is recited in the functional language, i.e., by what it does rather than what it is, it is incumbent upon Applicants, when challenged by the USPTO, to demonstrate that the prior art product does not actually possess those characteristics. With regard to the alleged 'potential role' of the als1 protein in the adhesion function, it should be noted that the instant specification acknowledges on page 10 (see last paragraph) that ALS1 gene product was already characterized 'as an adhesin' in the art at the time of the invention. Hoyer et al. (1995) taught the N-terminal fragment claimed in claim 9, i.e., the fragment encoded by nucleotides 52 to 1296 of the nucleotide sequence, SEQ ID NO: 7. It is well known in the art that a microbial protein fragment as long as the one taught by Hoyer et al. (1995) is long enough to serve intrinsically as an effective immunogen, being capable of producing an effective immune response in a patient, absent evidence to the contrary. As set forth below, the instantly claimed composition is obvious over Hoyer et al. (1995).

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# Rejection(s) under 35 U.S.C. § 112, Second Paragraph

- 18) Claims 1, 3 and 9 are rejected under 35 U.S.C § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.
- (a) Claim 1 is vague, indefinite, confusing and/or incorrect, and has improper antecedence in the recitation: 'the vaccine' (see line 4). Claim 1, as amended via line 1 of the claim, is drawn to a 'pharmaceutical composition', not to a 'vaccine'.
- (b) Claim 9 is indefinite, confusing and/or incorrect in the recitation: "SEQ ID NO: 7" without specifying that the recited SEQ ID number represents the nucleotide sequence. For the purpose of distinctly claiming the subject matter, it is suggested that Applicants replace the recitation 'SEQ ID NO: 7' with --the nucleotide sequence of SEQ ID NO: 7--.
- (c) Claims 3 and 9, which depend from claim 1, are also rejected as being indefinite because of the vagueness or indefiniteness identified above in the base claim.

# Rejection(s) under 35 U.S.C. § 102

19) Claims 1 and 3 are rejected under 35 U.S.C § 102(b) as being anticipated by Hoyer *et al.* (*J. Bacteriol.* 180: 5334-5343, October 1998, already of record).

The limitation: 'the vaccine produces an effective immune response in a patient' in claim 3 is not given any weight in this rejection since the claims, as amended, are not directed to a vaccine.

Hoyer's (1998) taught a composition, which comprises the purified N-terminal domain of Als1p protein of *Candida albicans* dissolved in PBS, i.e., a biocompatible carrier for injection or infusion (see pages 5336 and 5337).

Claims 1 and 3 are anticipated by Hoyer et al. (1998).

# Rejection(s) under 35 U.S.C. § 103

20) Claims 1, 3 and 9 are rejected under 35 U.S.C § 103(a) as being unpatentable over Hoyer *et al.* (*Mol. Microbiol.* 15: 39-54, 1995, already of record) (Hoyer *et al.*, 1995) in view of Applicants' admitted state of the prior art.

It is noted that the instant claims 1 and 3 do not structurally define the claimed protein fragment either by a molecular weight or by a specific SEQ ID number. The specification identifies an ASL1 protein of a strain of *Candida albicans* as having the amino acid sequence of SEQ ID NO: 8 which is encoded by the nucleotide sequence of SEQ ID NO: 7.

Hoyer et al. (1995) taught the N-terminal amino acid sequence of an isolated ASL1 protein of Candida albicans. See Table 1; Figure 5; and first paragraph in left column on page 44. A nucleotide sequence search performed in the Office revealed 100% sequence identity between nucleotides 52-1296 of

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the instantly recited SEQ ID NO: 7 and Hoyer's nucleotide sequence that encodes the N-terminal fragment of the ASL1 protein. An amino acid sequence search performed in the Office also showed that the prior art Hoyer's (1995) protein has 100% sequence identity with the amino acid sequence, SEQ ID NO: 8, of the instant application. See the attached sequence search reports. Although Hoyer et al. (1995) do not expressly recite their ALS1 protein to contain an adhesin binding site of Candida albicans, since the prior art protein is structurally identical to the instantly recited asl 1 protein, it is expected to have the adhesin binding site of Candida albicans. Hoyer et al. (1995) also envisioned that ALS1 to be involved in adhesion of the fungal pathogen to host cells (see paragraph bridging left and right columns on page 49). Additionally, Applicants acknowledge in the instant specification the following to be known in the art: the characterization of the gene product of the ALS1 gene to be an adhesin (see last paragraph on page 10 of the instant specification). Since the prior art N-terminal fragment is encoded by the nucleotides that are structurally identical to nucleotides 52 to 1296 nucleotides of the instantly recited SEQ ID NO: 7, it is expected to have the intrinsic ability to produce an effective immune response in a patient. The ability to produce an effective immune response in a patient is viewed as an uncharacterized functional property of Hoyer's (1995) N-terminal protein fragment encoded by nucleotides 52 to 1296 of SEQ ID NO: 7. Hover et al. (1995) expressly suggested raising an antibody to the N-terminal sequences of their ALS1 protein 'in order to verify location of the protein and degree and type of glycosylation' (see lines 5-8 in the left column on page 49).

Hoyer *et al.* (1995) do not appear to expressly teach a pharmaceutical composition comprising the N-terminal fragment of their ALS1 protein and a biocompatible carrier.

However, it is routine and conventional in the art to produce a pharmaceutical composition of an art-known protein fragment by mixing it with an art-known biocompatible or pharmaceutical carrier, such as saline. Given the express teaching or suggestion by Hoyer *et al.* (1995) to raise an antibody to the N-terminal sequences of the ALS1 protein, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to add an art-known biocompatible carrier, such as saline, to Hoyer's N-terminal fragment encoded by nucleotides 52 to 1296 of SEQ ID NO: 7 to produce the pharmaceutical composition of the instant invention, with a reasonable expectation of success. One of skill in the art would have been motivated to produce the instant invention for the expected benefit of producing a composition suitable for raising an antibody to Hoyer's (1995) N-terminal fragment in order to verify localization of the ALS1 protein and degree and type of glycosylation as taught by Hoyer *et al.* (1995).

Claims 1, 3 and 9 are *prima facie* obvious over the prior art of record.

#### Remarks

21) Claims 1, 3 and 9 stand rejected.

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Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax Center which receives transmissions 24 hours a day and 7 days a week. The RightFax number for submission of before-final amendments is (703) 872-9306. The RightFax number for submission of after-final amendments is (703) 872-9307.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (571) 272-0854. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 7.15 a.m. to 4.15 p.m. except one day each bi-week, which would be disclosed on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Lynette Smith, can be reached on (571) 272-0864.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

February, 2004

S. DEVI, PH.D. PRIMARY EXAMINER

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S60896
agglutinin-like protein - yeast (Candida albicans)
C;Species: Gandida albicans
C;Date: 27-Apr-1996 *sequence_revision 13-Mar-1997 *text_change 17-Mar-2006
                                                                                                                                                                                                          SEO 15 NO.81
                                S60896
                            C:Accession: S60896
R:Hoyer, L.L.; Scherer, S.; Shatzman, A.R.; Livi, G.P.
McI. Microbiol. 15, 39-54, 1995
A;Title: Candida albicans ALS1: domains related to a Saccharomyces cerevisiae sexual.
A;Accession: S60896
A;Accession: S60896
A:Status: preliminary
                          A;Accession: Source
A;Status: preliminary
A;Molecule type: DNA
A;Residues: 1-1260 <HOY>
A;Cross-references: EMBL:L25902; NID:g704426; PIDN:AAC41649.1; PID:g704427
C:Superfamily: yeart glucan 1.4-alpha-glucosidase homolog: 
                          A;Cross-references: EMBL:LZ>YUZ; NID:g/U44Zo; PIDN:AAC4ID4Y.I; PID:g/U44Z/
C;Superfamily: yeast glucan 1,4-alpha-glucosidase homolog; glucan 1,4-alpha-glucosida
                                                                                                       100.0%; Score 6495; DB 2; Length 1260; 100.0%; Pred. No. 1.7e-273; tive .0; Mismatches 0; Indels 0;
                               Best Local Similarity
                               Matches 1260; Conservative
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                        Ov
                                                            1 MLQQFTLLFLYLSIASAKTITGVFDSFNSLTWSNAANYAFKGPGYPTWNAVLGWSLDGTS 60 1 MLQQFTLLFLYLSIASAKTITGVFDSFNSLTWSNAANYAFKGPGYPTWNAVLGWSLDGTS 60
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61 ANPGDTFTLNMPCVFKYTTSQTSVDLTADGVKYATCQFYSGEEFTTFSTLTCTVNDALKS 120
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               Qу
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   Qν
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1021 TLSTTSNSITEDITTSQPTGDNGDNTSSTNPVPTVATSTLASASEEDNKSGSHESASTSL 1080
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Qy Db

Qy Db